TET-SOL 324- tetracycline hydrochloride powder, for solution Alpharma Inc. Animal Health

Tet-Sol® 324

INDICATIONS — CHICKENS

Control of chronic respiratory disease (CRD air sac disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli*; infectious synovitis caused by *Mycoplasma synoviae* susceptible to tetracycline hydrochloride.

RECOMMENDED DOSAGE LEVEL

Administer for 7-14 days.

CRD air sac disease

Use soluble powder in the drinking water at a drug level of 400-800 mg tetracycline hydrochloride per gallon per day

Infectious synovitis

Use soluble powder in the drinking water at a drug level of 200-400 mg tetracycline hydrochloride per gallon per day

INDICATIONS — TURKEYS

Control of infectious synovitis caused by *Mycoplasma synoviae*; bluecomb (transmissible enteritis, corona viral enteritis) complicated by organisms susceptible to tetracycline hydrochloride.

RECOMMENDED DOSAGE LEVEL

Administer for 7-14 days.

Infectious synovitis

Use soluble powder in the drinking water at a drug level of 400 mg tetracycline hydrochloride per gallon per day

Bluecomb

Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to provide 25 mg/pound of body weight per day in divided doses.

INDICATIONS — SWINE AND CALVES

Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli*; bacterial pneumonia associated with *Actinobacillus pleuropneumoniae*, *Pasteurella* spp., *Klebsiella* spp. susceptible to tetracycline hydrochloride.

RECOMMENDED DOSAGE LEVEL

Administer for 3-5 days.

Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to

provide 10 mg/pound of body weight per day in divided doses.

SPECIAL DIRECTIONS FOR BABY CALVES AND BABY PIGS

Administer this product 1 hour before or 2 hours after feeding milk or milk replacers. Provide clean (unmedicated) drinking water at all times.

WARNING

Do not slaughter birds or swine for food within 4 days of treatment or calves within 5 days of treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Not for use in turkeys or chickens producing eggs for human consumption.

Do not use for more than 5 consecutive days in swine and calves, or 14 consecutive days in birds.

DIRECTIONS FOR USE

Prepare fresh solutions at least once a day. Solutions are not stable for more than 24 hours. Use as a sole source of tetracycline. Deliver the recommended dosage level in divided doses. Medicate at first clinical signs of disease or when experience indicates the disease may be a problem. Diagnosis should be reconsidered if improvement is not noticed within 3 days. The concentration of drug required in medicated water must be adequate to compensate for variations in the age and class of animals, feed consumption, and environmental temperature and humidity, each of which affects water consumption.

MIXING DIRECTIONS FOR TURKEYS, SWINE AND CATTLE

40 oz dissolved in 8000 ml (approximately 2.1 gallons) of warm water will provide a stock solution of 100 mg of tetracycline hydrochloride activity per ml. This stock solution, when metered at approximately 1 ounce/gallon, will provide drinking water containing 2957 mg of tetracycline hydrochloride activity per gallon for turkeys. The contents of this packet are sufficient to deliver the recommended daily dosage levels as follows:

At 25 mg/pound of body weight – 32,400 total pounds of turkeys to be medicated in divided doses.

At 10 mg/pound of body weight – 81,000 total pounds of calves or swine to be medicated in divided doses.

Individual calf treatment – 5 ml (1 measuring teaspoonful) twice daily for each 100 pounds body weight administered as a drench or by dose syringe.

MIXING DIRECTIONS FOR CHICKENS AND TURKEYS

To arrive at the recommended dosages, prepare stock solutions as follows:

200 mg/gallon – dissolve 1 packet (40 oz) in 121,120 ml warm water (32 gallons)

400 mg/gallon – dissolve 1 packet (40 oz) in 60,560 ml warm water (16 gallons)

800 mg/gallon – dissolve 1 packet (40 oz) in 30,280 ml warm water (8 gallons)

These stock solutions should then be metered into drinking water at approximately 1 ounce per gallon. At 200-800 mg/gallon this packet will medicate 1012 to 4050 gallons of drinking water.

NOTE

This product is to be administered twice a day in the drinking water of swine, calves and poultry. One half of the recommended daily dosage level of antibiotic is to be consumed during each administration period, thus providing the drug in divided doses.

Each pound contains 324 g of tetracycline hydrochloride activity.

This package contains 810 g of tetracycline hydrochloride activity.

Store below 77°F (25°C.)

For Animal Use Only

Restricted Drug (California) - Use only as directed.

Net Weight 40 oz (1134 Grams)





Observe Label Directions

Alpharma Inc. Bridgewater, NJ 08807

33924BF 0903

NADA #65-140, Approved by FDA

Trademarks registered by Alpharma Inc.

PRINCIPAL DISPLAY PANEL - 1134 Gram Label

 $RUSSELL_{\circledR}$

Tetracycline Hydrochloride

Soluble Powder

Antibiotic

Tet-Sol[®] 324

For use in drinking water

For swine, calves, and poultry

Each pound contains 324 g of tetracycline hydrochloride activity.

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Store below 77° F (25° C)

For Animal Use Only

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Take Time Observe Label

Directions

Alpharma Inc. Bridgewater, New Jersey 08807 33924BF 0903 NADA #65-140, Approved by FDA Trademarks registered by Alpharma Inc. INDICATIONS - CHICKENS: Control of Chronic respiratory disease (CRD air sac disease) caused by Mycoplasma gailtsepticum and Escherichia coli; Infectious synovilla caused by Mycoplasma synovilla caused by Mycopl hydrochloride.

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Control of Infectious synovitis caused by Mycoplasma synoviae; bluecomb (transmissible enteritis, corons viral enteritis) complicated by organisms susceptible to tetracycline hydrochloride.

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Infectious synovitis: Use soluble powder in the drinking water at a drug level of 400 mg tetracycline hydrochloride per gallon per day

Bluecomb: Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to provide 25 mg/pound of body weight per day in divided dozes.

INDICATIONS - SWINE AND CALVES: Control and treatment of bacterial enteritis (scours) caused by Escherichia coil; bacterial preumonia essociated with Actinobacillus pleuropneumoniae, Pasteurella spp., Klebsiella spp. susceptible to tetracycline hydrochloride.

RECOMMENDED DOSAGE LEVEL: Administer for 3-5 days.

Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to provide 10 mg/pound of body weight per day in divided doses.

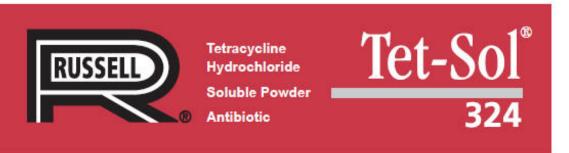
SPECIAL DIRECTIONS FOR BABY CALVES AND BABY PIGS: Administer this product 1 hour before or 2 hours after feeding milk or milk replacers. Provide clean (unmedicated) drinking water at all times.



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Net Weight 40 oz (1134 Grams)





Alpharma Inc. Bridgewater, NJ 08807

33924BF 0903 NADA#65-140, Approved by FDA



Tet-Sol

DIRECTIONS FOR USE: Prepare fresh solutions at least once a day. Solutions are not stable for more than 24 once a day, solutions are not state for more man 24 hours. Use as a sole source of tetracycline. Deliver the recommended dosage level in divided doses. Medicate at first clinical signs of disease or when experience indicates the disease may be a problem. Diagnosis should be reconsidered if improvement is not noticed within 3 days. The concentration of drug regulated in the contraction of drug regulated in the contraction. medicated water must be adequate to compensate for variations in the age and class of animals, feed consumption, and environmental temperature and humidity, each of which affects water consumption.

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PRINCIPAL DISPLAY PANEL - 10 pack Label

 $RUSSELL_{\circledR}$

Tetracycline Hydrochloride Soluble Powder

Antibiotic

Tet-Sol® 324

Follow directions for use and mixing instructions on packet label.

CAUTION: Not for human use / for oral use in animals only

Store below 77°F (25°C.)

Lot:

Exp.:

Contents: 10 packs, 40 oz (1134 grams) each

Take Time Observe Label Directions

List # 33924 33924CL 0912 Restricted Drug (California) - Use only as directed. NADA #65-140, Approved by FDA

Trademarks registered by Alpharma Inc.

Alpharma Inc.

Bridgewater, New Jersey 08807





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Bridgewater, New Jersey 08807

TET-SOL 324

tetracycline hydrochloride powder, for solution

Product Information			
Product Type	OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:46573- 217
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety Basis of Strength Ingredient Name Strength

Tetracycline Hydrochloride (UNII: P6R62377KV) (Tetracycline - UNII:F8VB5M810T) | Tetracycline Hydrochloride | 324 g in 0.45 kg

Product Characteristics			
Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46573-217-10	10 in 1 CONTAINER		

1 NDC:46573-217-26	1.134 kg in 1 PACKET			
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Marketing Category NADA	Application Number or Monograph Citation NADA065140	Marketing Start Date 01/01/2009	Marketing End Date	

Labeler - Alpharma Inc. Animal Health (070954094)

Establishment				
Name	Address	ID/FEI	Business Operations	
Alpharma Inc. Animal Health		090610770	MANUFACTURE, ANALYSIS, RELABEL, REPACK	

Revised: 5/2009 Alpharma Inc. Animal Health